

JAN 31 2005

Dynaflor Bypass Graft 51
Special 510(k)

Dynaflor Bypass Graft
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

K050049
p. 1 of 2

General Information:

Submitter Name: Bard Peripheral Vascular, Inc. (BPV)
[Wholly owned Subsidiary of C. R. Bard, Inc.]
Address: 1625 W. Third Street
P.O. Box 1740
Tempe, AZ 85280-1740
Telephone Number: (480) 894-9515 ext. 2836
Fax Number: (480) 449-2546
Contact Person: Glenn Norton
Date of Preparation: January 7, 2005

Device Information:

Device Trade Name: Dynaflor™ Bypass Graft
Common/Usual Name: Peripheral Vascular Bypass Graft
Classification Name: 74 DSY – Prosthesis, Vascular Graft, Of 6mm And Greater Diameter
21 CFR 870.3450 - Class II
Vascular graft prosthesis
Classification Panel: Cardiovascular

Predicate Device:

IMPRA Distaflor™ Bypass Graft, K983861, concurrence date 11/24/1998.

Summary of Change:

The modification to the Distaflor Bypass Graft incorporates a more smoothly contoured distal cuff to enhance the good blood flow performance of the predicate design, for improved hemodynamics at the distal anastomosis. The change increases the flow potential of the graft for larger anastomotic sites, such as found with a femoropopliteal above-the-knee bypass, and extra-anatomic bypass procedures (e.g., axillofemoral, femoral/femoral, and axillobifemoral). All other aspects of the modified device remain the same as the predicate.

Device Description:

The Dynaflor bypass graft has a pre-formed cuff at the distal end to promote good hemodynamic performance at the distal anastomosis. Dynaflor grafts are available in various lengths and diameters, with and without external support.

Intended Use of Device:

Dynaflor™ Bypass Grafts are intended for bypass or reconstruction of peripheral arterial blood vessels.

Technological Comparison to Predicate Device:

The technological characteristics of Dynaflo bypass grafts are substantially equivalent to those of the predicate Distaflor bypass graft in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

Non-Clinical Performance Data

Design verification of the modified device was done with conformance to or evaluated based on the following FDA guidance and industry recognized standards:

- *Guidance Document for Vascular Prosthesis 510(k) Submissions*, dated 11/01/2000
- ANSI/AAMI VP20-1994, *Cardiovascular Implants – Vascular Prosthesis*
- ANSI/AAMI/ISO 7198: 1998/2001, *Cardiovascular implants – Tubular vascular implants*
- AAMI/ANSI/ISO 10993-1: 1997, *Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- AAMI/ANSI/ISO 10993-7: 1995, *Biological evaluation of medical devices – Part 1: Ethylene Oxide Sterilization Residuals*
- AAMI/ANSI/ISO 11135:1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

Dynaflor Bypass Grafts met all the predetermined performance criteria of design verification as specified by applicable standards, guidance's, test protocols and/or customer inputs. Dynaflo Bypass Grafts are substantially equivalent to the legally marketed predicate device, the IMPRA Distaflor Bypass Graft, K983861, concurrence date 11/24/1998.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2005

Bard Peripheral Vascular, Inc.
c/o Mr. Glenn Norton
Assistant Project Manager
1625 W. 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K050049
Bard® Dynaflo™ Bypass Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II (two)
Product Code: DSY
Dated: January 7, 2005
Received: January 10, 2005

Dear Mr. Norton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Bram D. Zuckerman

 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1-B

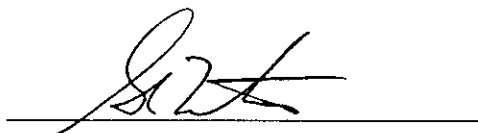
Dynaflor™ Bypass Graft
Special 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Regulatory Affairs Assistant Project Manager of Bard Peripheral Vascular, Inc., that this notification [510(k)] for the Dynaflor™ Bypass Graft is indicated for the following:

"Dynaflor™ Bypass Grafts are intended for bypass or reconstruction of peripheral arterial blood vessels."

Signature of 510(k) Submitter:



Printed Name of Submitter:

Glenn Norton

Date:

1/7/05

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

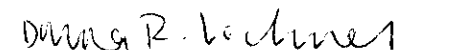
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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number

K050049

Division Sign-Off


Office of Device Evaluation